PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | ) | Confirmation No. 4950 |
| Arnold J. LEVINE *et al.* | ) | Group Art Unit: 1634 |
| Serial No.: 09/755,028 | ) | Examiner: B. Sisson |
| Filed: January 8, 2001 | ) | |
| For: P53-REGULATED GENES | ) | Docket No. 003848.00061 |

**RESPONSE TO OFFICE ACTION**

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated May 19, 2004, applicants request reconsideration of the patentability of the claims.

A petition for three-months extension of time accompanies this request in order to make it timely. It is believed that there is no additional fee due in connection with this response. However, should the Patent and Trademark Office determine that a fee is required, please charge our Deposit Account No. 19-0733.

Claims 31-41 and 67-70 are pending. All are rejected as failing to comply with the enablement and written description requirements of 35 U.S.C. §112, first paragraph.

Claim 31 is directed to a method for evaluating carcinogenicity. A test agent is contacted with a human cell, the level of expression of a gene product in the cell is determined, and an agent is identified as a potential carcinogen if it affects the expression of a particular gene in a particular direction. A group of genes is recited in the claims, each of which is identified by means of a "gene description." This is a verbal description of a gene that the art has used to describe the gene. Each gene description can be matched to a GenBank accession number by referring to Figs. 1A-1J and Figs. 2A-2J. GenBank accession numbers are not used within the claim. Each recited gene was already known in the art as of the effective filing date of the application.

The invention of claim 31 is not the discovery of a set of genes *per se*. The subject invention is a method of using a set of known genes.

Claim 67 identifies a set of transcripts by their GenBank accession numbers. Each of the GenBank accession numbers was assigned and publicly available prior to the effective filing date. Applicants' invention is a method of using transcripts or translation products of the known genes to evaluate carcinogenicity.

The Patent and Trademark Office urges that recitation of sequences of the recited genes is required in the specification to (a) demonstrate that the inventors possessed the claimed invention at the time of filing, and (b) teach those of skill in the art how to make and use the full scope of the invention without undue experimentation. As discussed below, a proper analysis of the facts demonstrates that the specification as filed complies with both requirements without

reciting sequences.

An objective standard should be applied to determine compliance with the written description requirement: "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

The specification names genes already known in the art and references each with a publicly available sequence in a U.S. government operated database. See Figs. 1A-1J and 2A-2J. Clearly, applicants were in possession of the invention. There can be no question that this is true. The Patent and Trademark Office has raised no reason to doubt that applicants possessed what they clearly name.

The Patent and Trademark Office seems to have taken the position that any time a gene or protein is recited, it must be defined by a sequence and provided in the application. This, however, is not the law. A known substance need not be described in any particular way. The only requirement is that the applicant convey that he invented what is claimed. Claims 31 and 67 are directed to methods. The methods employ known compositions. The compositions are not what is claimed, but rather a way of using them is claimed. Applicants adequately describe the methods claimed. Applicants' disclosure clearly conveys that they invented what is claimed.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent *coupled with information known in the art* without undue experimentation. A patent need not teach, and *preferably omits*, that which is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) (emphasis added); *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir.

1988) (emphasis added).

Applicants have omitted including the sequences of known genes in the specification. This comports with the *Buchner* exhortation of the Federal Circuit not to include that which is well known in the art. Since one evaluates enablement by considering both the disclosure and the information known in the art (*Telectronics, supra*) the omission of sequences of known genes is of no importance. Those of skill in the art do not approach a patent in a vacuum. Those of skill in the art are presumed to have knowledge that is available in the art. Therefore, the omission of the known sequences does not negatively impact enablement.

Two *Wands* factors outweigh the others in the present case:

(1) The state of the prior art.

(2) The amount of direction provided by the inventor.

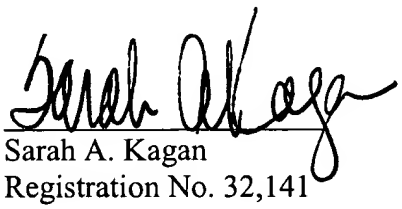
The prior art contained a description of each of the genes by sequence. The inventor pointed the reader directly to those sequences by providing GenBank accession numbers in the specification. This combination of facts does not leave any undue experimentation to be done; it leaves no experimentation to be done.

The Patent and Trademark Office has asserted that undue experimentation would be required but has not suggested what the nature of that would be. Those of skill in the art would not need to perform any experimentation to ascertain the sequences. "Point-and-click" is simply not undue experimentation.

Reconsideration of these dual rejections under 35 U.S.C. §112 is respectfully requested.

Respectfully submitted,

Dated: November 17, 2004

By: 

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